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(54) Title: BACTERICIDAL COATINGS FOR IMPLANTS

(57) Abstract

Metallic and ceramic implants provided with thin films of infection resistant coatings, such as external fixation devices, pins, metallic urological catheters, ceramic counterfaces in joint replacements, connectors and the like, a dry coating method therefor and apparatus to accomplish the same are disclosed. The thin films of bacteriostatic and/or fungistatic compounds on the implants are intended to further improve their biocompatibility by reducing infections, whether hospital induced or brought about by the indwelling nature of these devices. The method essentially includes the dry caoting of the outside surfaces of the metallic and ceramic implants with a thin film of bacteriostatic and/or fungistatic compounds. The apparatus to effect the method essentially includs a vacuum chamber, an evaporator and an ion source mounted in oeprative association within the chamber, and means for rotatably mounting a plurality of implants for exposure to the evaporator and the ion source.

* (Referred to in PCT Gazette No. 14/1993, Section II)

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BACTERICIDAL COATINGS FOR IMPLANTS

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to implants and, more particularly, to implants provided with bactericidal coatings so as not only to improve their antimicrobial properties, but also to make the implants fight germinating bacteria *in situ*.

2. The Prior Art

In a related co-pending application Serial No. 07/663,361, filed March 1, 1991, of Mohammed Farivar and Piran Sioshansi, entitled "Metallized Polymeric Implants, Methods and Apparatus," and assigned to a common assignee, Spire Corporation, Bedford, Massachusetts, there are disclosed and

claimed surface metallized polymeric implants, a method and an apparatus to improve the implants' biocompatibility and to reduce infusion-associated phlebitis and infection, twin commendable goals pulling in opposing direction. The disclosure of said application Serial No. 07/663,361 is incorporated herein by reference.

For, efforts directed at fighting infection, the overriding consideration of this invention, does of necessity reduce biocompatibility. The balancing of these two goals is a delicate test facing the medical practitioner.

In applications where the implant is intended for relatively short dwell time within the body, in particular in the use of external fixation devices to immobilize a broken limb while it heals, infection-fighting ability of the device becomes paramount at the expense of biocompatibility. This is what is addressed by this invention.

Infections, such as nosocomial infections (infections originating in a hospital), result from polymeric, metallic and/or ceramic implanted devices, including external fixation devices, indwelling urological catheters and the like, being placed in the body. Medical device manufacturers have not employed bacteriostatic compounds as antimicrobial agents in such indwelling devices because of the difficulties associated with producing an adherent, long lasting film on such poly-

meric, metallic and/or ceramic surfaces. It has been noted that using ion- beam-assisted deposition technique (IBAD), well-adhering, ductile thin films of bacteriostatic/fungistatic compounds also can be applied to biomedical products.

The common assignee herein, Spire Corporation of Bedford, Massachusetts, has been one of the pioneers in the field of ion beam technology. A plasma-supported ion beam technique for coating industrial cutting tools with a thin layer of cubic boron nitride to improve the tools' cutting properties is disclosed in U.S. Patent No. 4,440,108, of Roger G. Little et al, granted April 3, 1984, and assigned to said Spire Corporation. A plasma-ion deposition process of large-grain, thin semiconductor films directly on low-cost amorphous substrates is disclosed in U.S. Patent No. 4,443,488, also of Roger G. Little et al, granted April 17, 1984 and assigned to said Spire Corporation. A process of preventing surface discoloration in titanium orthopaedic implants by ion implantation is disclosed in U.S. Patent No. 4,693,760 of Piran Sioshansi, granted September 15, 1987 and assigned to said Spire Corporation. An ion implantation process for plastics to enhance their surface hardness and their resistance to chemical attack is disclosed in U.S. Patent No. 4,743,493 of Piran Sioshansi et al, granted May 10, 1988 and assigned to said Spire Corporation. A process for passivating the elec-

trochemically active surface of metal alloys so as to inhibit their corrosion is disclosed in U.S. Patent No. 4,743,308 of Piran Sioshansi et al, granted May 10, 1988 and assigned to said Spire Corporation. A sputter-enhanced ion implantation process, primarily of ball bearings, without the use of a separate evaporation system is disclosed in U.S. Patent No. 4,855,026 of Piran Sioshansi, granted August 8, 1989 and assigned to said Spire Corporation. An improved method and apparatus for the uniform ion implantation of spherical surfaces, such as ball bearings, is disclosed in U.S. Patent No. 4,872,922 of Stephen N. Bunker et al, granted October 10, 1989 and assigned to said Spire Corporation. A method of depositing an ionized cluster on a substrate is disclosed in U.S. Patent No. 4,152,478 of Toshinori Takagi, granted May 1, 1979. And a method of coating a substrate with a stoichiometric compound is disclosed in U.S. Patent No. 4,281,029 of Toshinori Takagi et al, granted July 28, 1981. The use of ion beam processing is thus well known and widespread.

SUMMARY OF THE INVENTION

It is a principal object of the present invention to overcome the above disadvantages by providing polymeric, metallic and ceramic implants with well adhering thin films of bactericidal compounds so as to render them infection fighting during their indwell time.

More specifically, it is an object of the present invention to provide polymeric, metallic and ceramic implants with thin films of bactericidal compounds, such as external fixation devices, skeletal fixation pins, catheters of all sorts, stents, laryngectomy flaps, tracheostomy tubes, hydrocephalic shunts, percutaneous connectors, hemodialysis ports, voice prosthesis, wound drainage devices, dental implants, closed looped ventilation tubes, ceramic and metallic counterfaces in joint replacements and the like.

The biomedical implant essentially comprises an implant of the above-enumerated group, a coating of bactericidal compound enveloping the same, with the bactericidal compound being formed as one or more of the following: platinum, iridium, gold, silver, mercury, copper, iodine, alloys, compounds and oxides thereof, the bactericidal coating being formed thereon in the form of ionized atoms of the compound within a vacuum chamber by ion-beam-assisted deposition (IBAD), with the chamber including an ion source and an evaporator.

Other objects of the present invention will in part be obvious and will in part appear hereinafter.

The invention accordingly comprises the polymeric, metallic and/or ceramic implants provided with coatings of bactericidal compounds of the present disclosure, its components, parts and their interrelationships, the scope of which will be indicated in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

For a fuller understanding of the nature and objects of the present invention, reference is to be made to the following detailed description, which is to be taken in connection with the accompanying drawings, wherein:

FIG. 1 is a flow diagram of a preferred process of applying the bactericidal compound coating to an implant;

FIG. 2 is a schematic diagram of a preferred apparatus useful for applying the bactericidal compound coating to an implant;

FIG. 3 is a schematic illustration of a typical intravenous infusion system in use;

FIG. 4 illustrates a typical polymeric cannula for use in cardiovascular monitoring of a patient;

FIG. 5 is a schematic illustration of a modified part of the apparatus shown in FIG. 2, illustrating the dry coating of a plurality of polymeric catheters;

FIG. 6 is a view similar to FIG. 6 but illustrates the dry coating of a full length polymeric catheter;

FIG. 7 is a longitudinal cross section, on an enlarged scale, of a polymeric catheter tip dry coated according to the invention;

FIG. 8 is a section of the catheter tip shown in FIG. 7 in the direction of the arrows 8-8;

FIG. 9 is a picture of a limb below the knee to which an external fixation device, not provided with a bactericidal coating according to the invention, has been secured;

FIG. 10 is a fragmentary vertical section of a humerus with an intramedullary fixation nail, which has been provided with a bactericidal coating according to the invention, implanted therein;

FIG. 11 is a picture of an external fixation pin, not provided with a bactericidal coating, on an enlarged scale, showing the signs of infection; and

FIG. 12 is a picture of a part of the infected area, on an enlarged scale, on the external fixation pin of FIG. 11.

Detailed Description of the Preferred Embodiments

In said co-pending application Serial No. 07/663,361, entitled "Metallized Polymeric Implants, Method and Apparatus", and assigned to said common assignee, Spire Corporation, Bedford, Massachusetts, there have been disclosed and claimed surface metallized polymeric implants, a method and an apparatus designed to render such polymeric implants biocompatible by reducing their infusion associated phlebitis and infection, the disclosure of which has been incorporated herein by reference.

The present invention, in general, relates to polymeric metallic and/or ceramic implants provided with well-adhering coatings of bactericidal compounds. The bactericidal compound coatings are not only infection resistant, but provide the implants with effective bacteria fighting attributes during their use as external fixation devices, pins, catheters of all types, ceramic and metallic counterfaces in joint replacements, percutaneous, connectors and the like.

The coatings of bactericidal compounds are formed on the surface of the implants in the form of ionized atoms of the compounds. Although the process of forming these bactericidal coatings is similar in application to that disclosed in said

co-pending application Serial No. 07/663,361, the herein preferred operational parameters are as follows: a vacuum pressure of about 10^{-7} torr, an ion beam current density from about 0.21 to about 5.67 NA/cm², with the temperature of the implant during ion-beam-assisted deposition (IBAD) ranging from about -76°C to about 200°C, ion beam energy ranging from about 200 eV to about 20,000 eV, and a deposition rate on the surface of the implant being from about 10 to about 1,000 Angstroms per second. The preferred deposition thickness of the bactericidal coatings on the implants ranges from at least about 0.01 micron to about 2 microns.

Further, any ion beam apparatus capable of ion-beam assisted deposition can be used to provide the implants with the bactericidal coating compounds according to the invention. Such apparatus must have as a minimum, a vacuum chamber provided with an evaporator and an ion source.

The bactericidal compound is formed as one or more of the following: platinum, iridium, gold, silver, mercury, copper, iodine, and alloys, compounds and oxides thereof. In particular we have found that the ionized oxides of silver and gold do make for excellent bactericidal coatings and in addition, they also enhance the implants' physical appearance.

In an article recently published in the March 1991 issue

of Orthopedics, Vol. 14, No. 3, "Factors in Pin Tract Infections," pp. 305-308, John Mahan, M.D. et al, state that in the use of skeletal external fixation devices (one being illustrated in FIG. 9 herein), the most significant complication is pin tract infection. The findings of these doctors show that, on examinations at the time of fixator removal, over 40% of the pin tracts were inflamed and about 75% of the pin tips cultured positive for bacteria. The predominant organism cultured was Staphylococcus epidermidis considered non-virulent, followed by virulent Staphylococcus aureus and Escherichia coli. Their findings indicate that the bone-pin construct is not a sterile interface isolated from the environment. Rather it is a conduit between the surface of the skin, normally colonized by bacteria, and the medullary cavity, which is normally not. The bone-pin interface is subject to repetitive loading, which mechanical environment influences the bacterial colonization of the pin. The authors of the study hint at therapeutic manipulation of the bone-pin interface as a rational next step "in reducing the considerable complications attributed to infection of skeletal fixation pins." Id, at p. 308.

Applicants have come up with a better product which not only confers bacterial resistance to polymeric, metallic and/or ceramic medical implantable devices, but also provides

such devices with a bactericidal coating which effectively fights bacteria itself, contributing thereby significantly to reducing pin tract infections.

THE EMBODIMENTS OF FIGS. 1 and 2

A flow diagram 10 of a preferred process of providing a bactericidal coating to polymeric, metallic and/or ceramic implants is illustrated in FIG. 1. The process essentially comprises the steps of providing 12 such an implant, mounting 14 the implant on a substrate holder, introducing 16 the implant *via* the substrate holder into a low-vacuum antechamber, evacuating 18 the low-vacuum antechamber to a high vacuum, further introducing 20 the implant *via* the substrate holder into a high-vacuum processing chamber, and forming 22 a thin coating of a bactericidal compound on the surface of the implant by a dry coating method within the high-vacuum processing chamber. Preferably, the dry coating method is an ion-beam process, such as an ion-beam-assisted deposition (IBAD) process. As known, ion beam processes are low-temperature, high-technology processes with excellent quality control to achieve good adherence, ductility, reproducibility, reliability and thickness of deposition control at a high throughput and with no chemical residues,

thus being both environmentally and occupationally a safe, dependable technique.

A schematic diagram of a preferred apparatus 30 for practicing the above-described process is illustrated in FIG. 2. Apparatus 30 is designed to provide biomedical polymeric, metallic and/or ceramic implants with infection fighting coatings. The implants include external fixation devices, skeletal fixator pins, catheters of all sorts, stents, faryngectomy flaps, tracheostomy tubes, hydrocephalic shunts, percutaneous connectors, ceramic and metallic counterfaces in joint replacements and the like. Apparatus 30 essentially comprises a vacuum chamber system 32 formed of a low-vacuum antechamber 34 and a high vacuum processing chamber 36, air-tightly separated from each other by a gate 38 movable between a shown open position and a closed position shown in dashed lines.

An ion source 40, which can be a bucket type ion source, is mounted within the high-vacuum processing chamber 36 in a position diametrically opposed to the low-vacuum antechamber 34, substantially as shown. As known, the source 40 of ions is fed by one or more gases, such as argon, oxygen, neon and/or helium, from a suitable gas supply source 42, via a mass flow controller 44, regulating the rate of gas feed. A filament power supply 46 is provided to supply current to the

filaments, an arc supply 48 to maintain an arc discharge between the anode and the filaments, an exit power supply 50 to accelerate the ions through the accelerator grid of the multiple grid system of the bucket type ion source 40, and a suppressor power supply 52 for negatively biasing the suppressor grid of the ion source 40 to reduce backstreaming of secondary electrons from the substrate.

An evaporator 60 also is mounted in the high-vacuum processor chamber 36 in operative association with the ion source 40. The evaporator 60 is designed to vaporize particular metallic evaporants so as to dry-coat a specific substrate therewith, being assisted in the dry-coating by an ion beam 62 emanating from the ion source 40. Metallic evaporants include mercury, copper, platinum, aluminum, nickel, iridium, silver, gold, and their respective alloys, oxides and compounds. A vapor shutter 64, designed to be rotated in and out of place of the evaporator 60, shields the substrates from the evaporants when in place. Substrates 66 to be dry-coated are introduced into the vacuum chamber system 32 of the dry-coating apparatus 30 with the aid of a suitable substrate holder 68. Preferably, the substrate holder 68 is mounted for both rotational and translatory motion on a shaft 70 and is introduced into the antechamber 34 through a hinge-like

mounted end-plate 72. A pivotable shutter 74 is provided to shield the substrates 66 from the ion beam 62, when desired. A thickness monitor 76 preferably is provided in operative association with the substrate holder 68 to monitor the thickness of the thin metallic film being deposited on the substrate 68 during operation of the dry-coating apparatus 30.

The Embodiments of FIGS. 3-8

In FIG. 3, a typical intravenous (I.V.) infusion system 80 is shown in operative use admitting a fluid 82 into an arm of a patient. If desired, other substances also can be added to the fluid 82 via a hypodermic needle 84 connected to the I.V. system 80. In this I.V. system 80, only the cannula 86 hereof is inserted into the vascular system of the patient. Hence only this cannula 86 portion of the system 80 need to be dry-coated with the thin bactericidal film. Other catheters 88 and 90, such as illustrated in FIGS. 4 and 6, are designed to be inserted substantially along their axial lengths, however, such as cardiac catheters and pulmonary artery catheters. Some of such catheters are formed with more than one lumen.

The dry-coating of polymeric catheter tips 86 and catheters 88 is illustrated in FIG. 5. As may be observed, the

substrate holder 68 is formed as a cage, which is lengthwise adjustable and is lengthwise provided with a plurality of mandrils 92 to accommodate and securely hold a plurality of catheter tips 86 and catheters 88 respectively thereon. The substrate holder 68 preferably is rotated during the coating operation and is designed to be moved in translation between the antechamber 34 and the high-vacuum processing chamber 36 prior to the coating operation.

The dry-coating of the entire length of a rather long polymeric catheter 90 is illustrated in FIG. 6. A frame 94 is shown being mounted to the end of the shaft 70. Depending on the relative sizes of the catheter 90 versus the frame 94, one or more catheters 90 are loosely wound about the frame 94. Longer catheters or a number of catheters can be processed on larger frames 94.

A polymeric catheter tip 96, dry-coated according to the invention and on an enlarged scale, is illustrated in section in FIGS. 7 and 8. The dry-coated polymeric catheter tip 96 comprises a polymeric catheter tip 98, coated on its outside surface as well as on its front beveled end with a bactericidal thin film 100. It will be observed that a small section on the inside front surface of the polymeric catheter tip 98 also is coated with a thin bactericidal film 102. It is to be pointed out that the thin bactericidal film 100 on

the outside of the polymeric catheter tip 98 is of even thickness from about 0.5 microns to about ten (10) microns, whereas the thin bactericidal film 102 on the inside of the tip 98 is tapered and usually does not extend beyond the widest angle of the ion beam 62, as illustrated.

The thin bactericidal coatings 100 are not only of uniform thickness circumferentially and along the axial length of the catheter tip 98, the coatings also are characterized by being dense, free of pinholes, strongly adherent, hard yet flexible, clean and free of contaminants. Due to the ion beam assisted process, the desired thickness of the bactericidal coatings 100 is precisely controllable and adjustable, is reliable and reproducible. The dry-coating method, furthermore is environmentally safe, with no chemical residue being produced as a consequence of the process.

The Embodiments of FIGS. 9-12

In the embodiments of FIGS. 9-12, representative biomedical components made from a metallic material, such as stainless steel, and designed, at least in part, to enter the human body are illustrated.

Specifically, FIG. 9 is a picture 110 of a limb 112 whose skeletal fracture has been stabilized by an external fixation device 114. The external fixation device 114, preferably

formed of stainless steel, has not been provided with a coating of bactericidal compounds according to the invention so as to illustrate the consequences thereof. The external fixation device 114 essentially comprises a plurality of 3/4 rings 116, each securing at least two transfixion pins 118 passing through the limb 112 and thereby stabilizing the affected internal skeletal fracture segments. It is primarily these pins 118 that cause the pin tract infections. The rings 116 are secured to one another by three threaded connecting rods 120.

FIG. 10 illustrates a humerus 130 in fragmentary vertical section, with an intramedullary fixation nail 132 implanted in its intramedullary canal 134 and secured therein by suitable screws 136. The intramedullary fixation nail 132 and its associated screws 136, preferably all formed of surgical stainless steel, have been provided with coatings 138 of bactericidal compounds in the form of ionized atoms thereof according to the invention. These thin coatings 138, not visible to the naked eye, are of an infection fighting compound as above described.

FIGS. 11 and 12 are reproductions of pictures taken from one of the above-mentioned articles, to wit, John Mahan, M.D., et al, "Factors in Pin Tract Infections," published in the March 1991 issue of Orthopedics, Vol. 14, No. 3, page 306.

FIG. 11 is a photograph 140 showing the surface of an external fixation pin 142, which like the transfixion pins 118 in Fig. 9, have not been provided with a bactericidal coating according to the invention, after removal from a patient, and illustrating visible signs of infection, as at 144. FIG. 12 is a photograph 150, on an enlarged scale, of a portion of the infected area on the pin 142 of FIG. 11.

Each of the metallic biomedical components illustrated in FIGS. 9-12, to wit, the external fixation device 114 and its components 116 and 118, as well as the intremedullary fixation nail 132 and its fixation screws 136, as well as the fixation pin 142 can all be dry-coated with the bactericidal coatings in an apparatus 30, as illustrated in FIG. 2 and provided with suitable fixtures 68 and 94 as illustrated in FIGS. 5 and 6, and adapted to hold and to present the implants to an ion beam 62, as above described.

As mentioned by John Mahan, M.D., et al in their said article, "The most significant complications in external fixation is pin tract infection (Figs 1-2). Rates ranging from .5% to 10% have been reported." Of the more than 200 pins removed from about 40 patients, they report that more than 40% of the pin tracts were inflamed and about three-quarters of the pin tips cultured positive for bacteria. "The predominant organism cultured was Staphylococcus epidermidis

(90.6%), considered non-virulent, followed by virulent _Staphylococcus aureus_ (37.5%), and _Escherichia coli_ (9.4%)." It is the bacillus _Escherichia coli_ that is illustrated in FIG. 12.

The illustrated biomedical components are merely representative of this class, which also includes metallic needles, metallic urological catheters, metallic percutaneous connectors and ceramic and metallic counterfaces in joint replacements, such as for the hip or the knee. Thus, all biomedical components, formed of polymer, metal or ceramic, designed to penetrate or enter into the body, are included herein. Most of the metallic biomedical components are formed of surgical stainless steel. Others are formed of titanium and cobalt-chromium. The bactericidal film 138 formed of a bactericidal compound can be readily applied in a reproducible, adherent manner to all known biomedical materials. The bactericidal compounds used to form the infection fighting film 138 according to the invention include: tungsten, titanium, platinum, iridium, gold, silver, mercury, copper, iodine, and their respective known alloys, compounds and oxides.

The process of the invention, as above described with reference to FIGS. 1 and 2, of providing biomedical components with the infection fighting film 138, preferably is carried out with the following operating parameters: a vacuum

pressure of about 10^{-7} torrs, an ion beam current density from about 0.21 NA/cm^2 to about 5.67 NA/cm^2, with the substrate temperature ranging from about -76° C to about 200° C, an ion beam energy from about 200 eV to about 20 Kev, and with a deposition rate on the substrate ranging from about 10 Angstroms/second to about 1000 Angstroms per second.

EXAMPLE I

An external fixation device 114, in particular the trans-fixion pins 118 thereof, have been dry-coated in the apparatus 30 and in accord with the above-described process with the following operational parameters:

Evaporant:	Ag
Deposition Rate:	5.0 nm/sec.
Ion Beam Energy:	5 keV
Current Density:	27.5 microamps/cm^2
Substrate Temperature:	15° C
Ion Beam:	0^+
Thickness of Bactericidal Film Being Deposited:	1.0 micron
Processing Time:	3 min., 20 sec.
Vacuum Pressure in Processing Chamber:	10^{-6} torr

EXAMPLE II

A metallic urological catheter has been dry-coated over its entire length in the apparatus 30 and in accord with the above-described process, employing the following operational parameters:

Evaporant:	Ti
Deposition Rate:	7.5 nm/sec.
Ion Beam Energy:	5 keV
Current Density:	27.5 microamps/cm^2
Substrate Temperature:	25° C
Ion Beam:	Ar^+ and O^+
Thickness of Bactericidal Film Deposited:	0.5 micron
Processing Time:	1 min., 12 sec.
Vacuum Pressure in Processing Chamber:	10^{-6} torr

EXAMPLE III

A ceramic counterface has been dry-coated over its entire length in the apparatus 30 and in accord with the above-described process, employing the following operational parameters:

Evaporant:	Au
Deposition Rate:	5.0 nm/sec.
Ion Beam Energy:	10 KeV
Current Density:	42.4 uA/cm^2
Substrate Temperature:	20°C
Ion Beam:	O^+ and Ar
Thickness of Bactericidal Film Deposited:	1.2 micron
Processing Time:	3 min., 50 secs.
Vacuum Pressure:	10^{-7} torr

EXAMPLE IV

A polymeric central venous stent has been dry-coated over its entire length in the apparatus 30 and in accord with the above-described process, employing the following operational parameters:

Evaporant:	Ag
Deposition Rate:	7 nm/sec.
Ion Beam Energy:	10 keV
Current Density:	200 uA/cm^2
Substrate Temperature:	10°C
Ion Beam:	Ar^+ and O^+
Thickness of Bactericidal Film Being Deposited:	1.0 micron
Processing Time:	2 min., 15 sec.
Vacuum Pressure in Processing Chamber:	10^{-7} torr

Thus it has been shown and described polymeric, metallic and/or ceramic implants provided with bactericidal compounds which implants satisfy the objects and advantages set forth above.

Since certain changes may be made in the present disclosure without departing from the scope of the present invention, it is intended that all matter described in the accompanying drawings, be interpreted in an illustrative and not in a limiting sense.

What is claimed is:

1. A biomedical component comprising:

(a) a component; and

(b) a coating of bactericidal compound formed on said component in the form of ionized atoms of said compound.

2. The biomedical component of claim 1 wherein said component is one of a group consisting of external fixator devices, needles, catheters, stents, percutaneous connectors, IUD's, tracheostomy tubes, hemodialysis ports, shunts, voice prosthesis, dental implants and ceramic and metallic counterfaces in joint replacement.

3. The biomedical component of claim 1 wherein said coating of bactericidal compound is formed of one or more of the following: platinum, iridium, gold, silver, mercury, copper, iodine, and alloys, compounds, and oxides thereof.

4. The biomedical component of claim 1 wherein said component is a pin used in an external fixator device, and wherein said coating of bactericidal compound is an ionized oxide of silver.

5. The biomedical component of claim 1 wherein said component is a ring used in an external fixator device, and wherein said coating of bactericidal compound is an ionized deposit of gold.

6. The biomendical component of claim 1 wherein said coating of said bactericidal compound formed on said compound is formed thereon by ion-beam-assisted deposition in a vacuum chamber.

7. The biomedical component of claim 1 wherein said ion-beam-assisted deposition in said vacuum chamber is carried out with the following operating parameters: a vacuum pressure of about 10^{-7} torr, an ion beam current density from about 0.21 to about 5.67 NA/cm^2, with the temperature of said component ranging from about -76°C to about 200°C, an ion beam energy from about 200 eV to about 20 keV, and with a deposition rate of about 10 Angstroms/second to about 1000 Angstroms/second.

8. A biomedical implant comprising:

(a) an implant being one of a group consisting of external fixator devices, needles, urological catheters, stents, percutaneous connectors, and ceramic and metallic counterfaces in joint replacement;

(b) a coating of bactericidal compound enveloping said implant;

(c) said coating of said bactericidal compound being formed of one or more of the following: platinum, iridium, gold, silver, mercury, copper, iodine, and alloys, compounds and oxides thereof;

(d) said coating of said bactericidal compound being formed on said implant in the form of ionized atoms of said compound.

9. The biomedical implant of claim 8 wherein said coating of bactericidal compound on said implant is formed by ion-beam-assisted deposition within a vacuum chamber provided with an ion source and an evaporator.

10. The biomedical implant of claim 9 wherein said ion-beam-assisted deposition is carried out with the following operating parameters: a vacuum pressure of about 10^{-7} torr, an ion beam current density from about 0.21 to about 5.67 NA/cm², with the temperature of said component ranging from about -76° C to about 200° C, an ion beam energy from about 200 eV to about 20keV, and with a deposition rate of about 10 Angstroms/second to about 1000 Angstroms/second.

11. A biomedical implant comprising:

(a) an implant being one of a group consisting of an external fixation device and a catheter;

(b) a layer of bactericidal compound formed on said implant in the form of ionized atoms of said compound;

(c) said layer of bactericidal compound being one of a group consisting of ionized oxide of silver and gold;

(d) said layer of bactericidal compound being formed on said implant by ion-beam-assisted deposition within a vacuum chamber.

12. The biomedical implant of claim 11 whereas said ion-beam-assisted deposition is carried out with the following operating parameters: a vacuum pressure of about 10^{-7} torr, an ion beam current density from about 0.21 to about 5.67 NA/cm^2, with the temperature of said component ranging from about -76°C to about 200°C, an ion beam energy from about 200 eV to about 20 keV, and with an evaporation rate of about 10 Angstroms/second to about 1000 Angstroms/second.

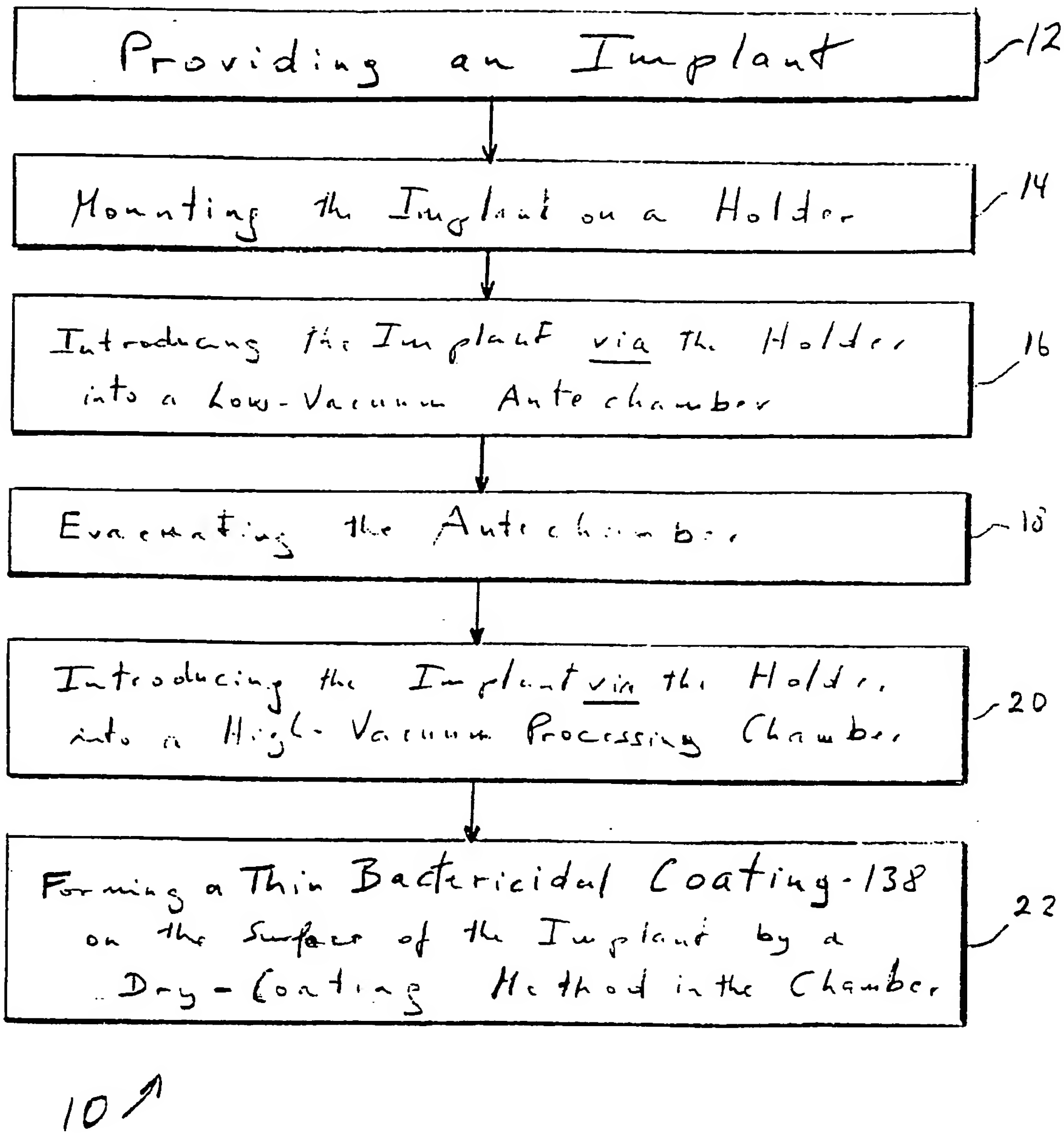
Providing an Implant
12
Mounting the Implant on a Holder
14
Introducing the Implant via the Holder into a Low-Vacuum Antechamber
16
Evacuating the Antechamber
18
Introducing the Implant via the Holder into a High-Vacuum Processing Chamber
20
Forming a Thin Bactericidal Coating-138 on the Surface of the Implant by a Dry-Coating Method in the Chamber
22
10

FIG. 1

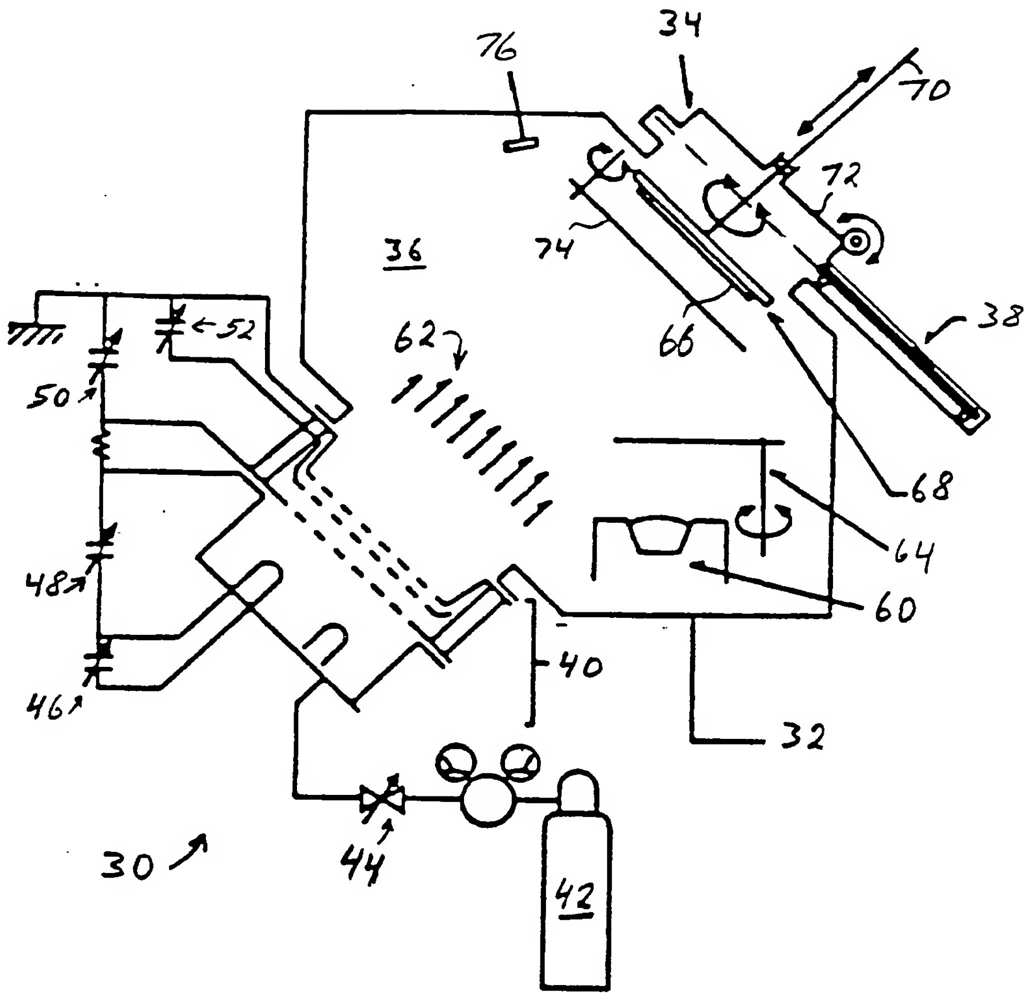

FIG. 2

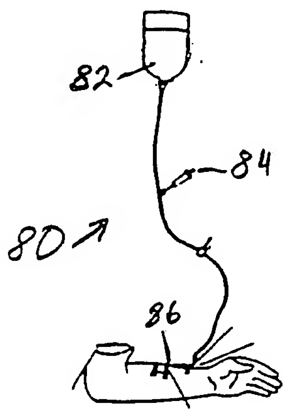

FIG. 3

FIG. 4

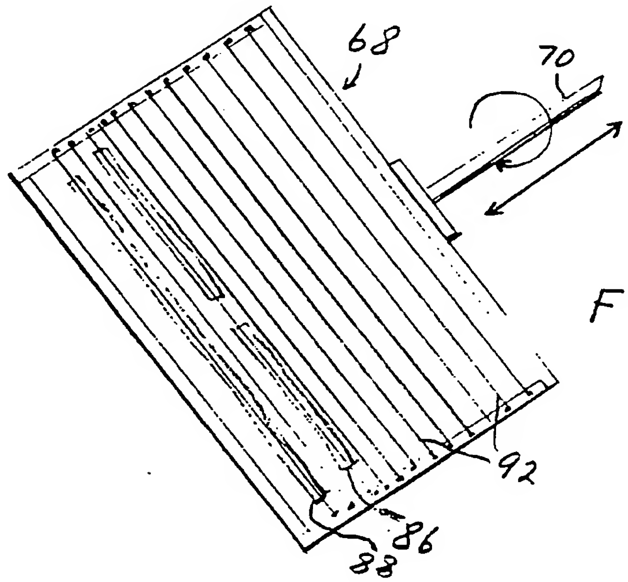

FIG. 5

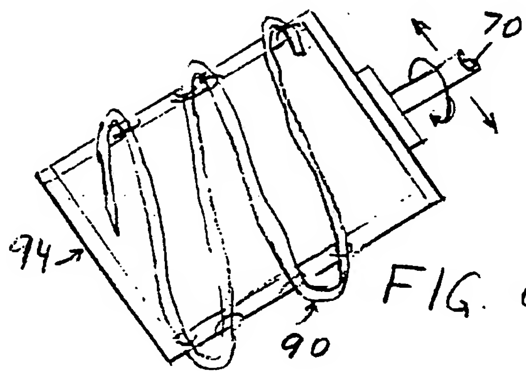

FIG. 6

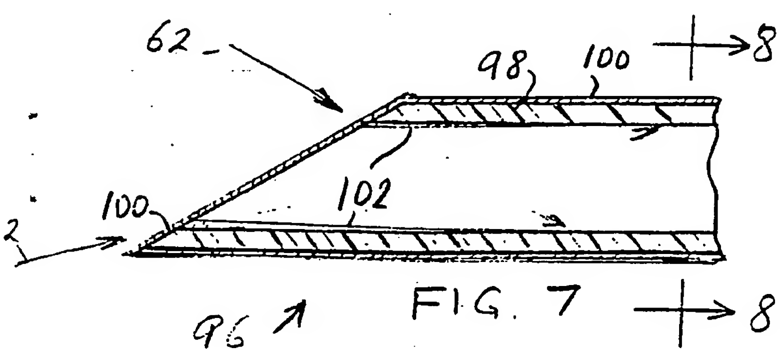

FIG. 7

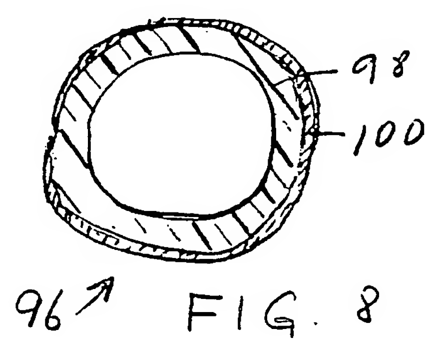

FIG. 8

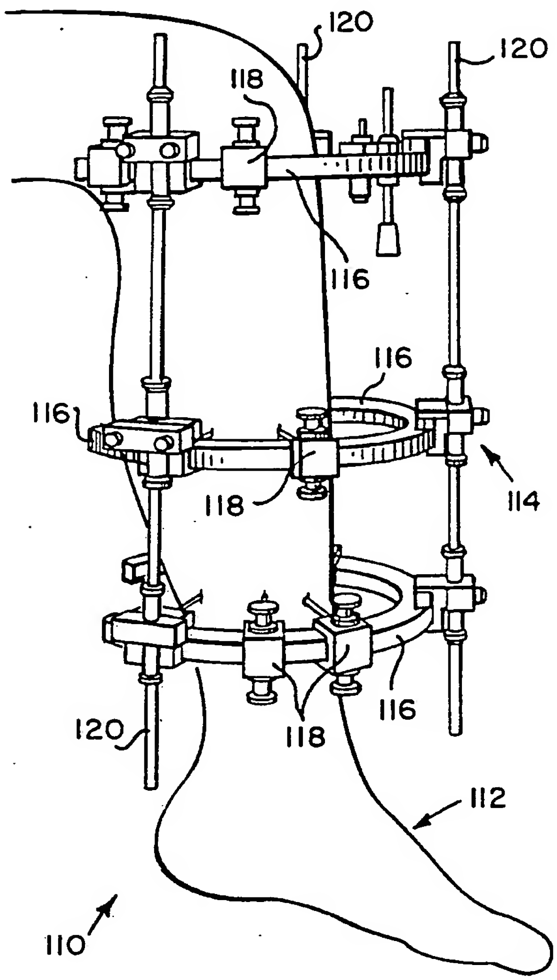
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Fig. 9

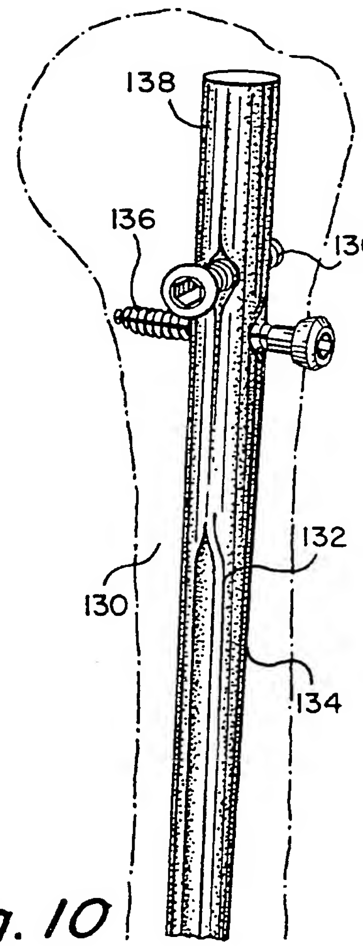
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Fig. 10

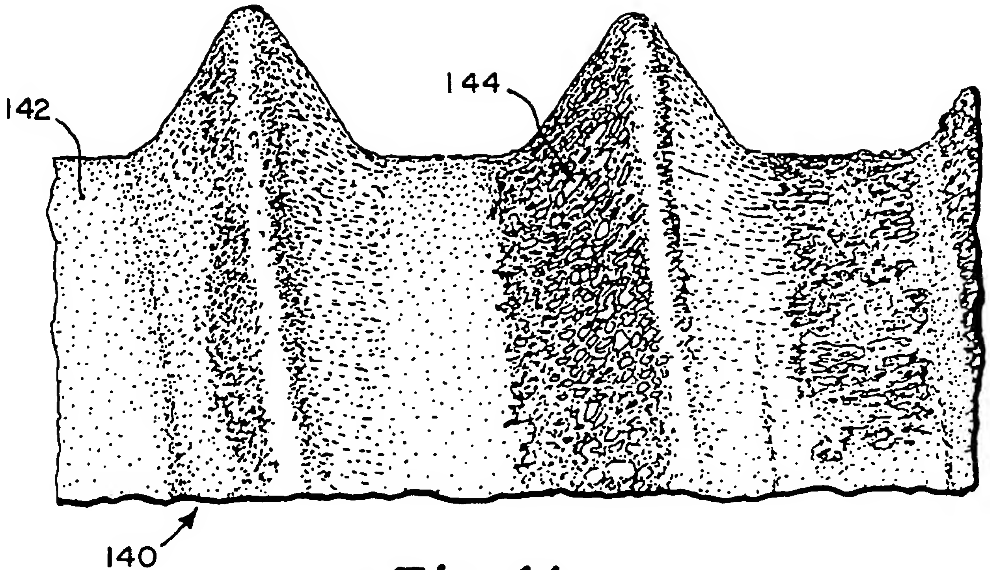

Fig. 11

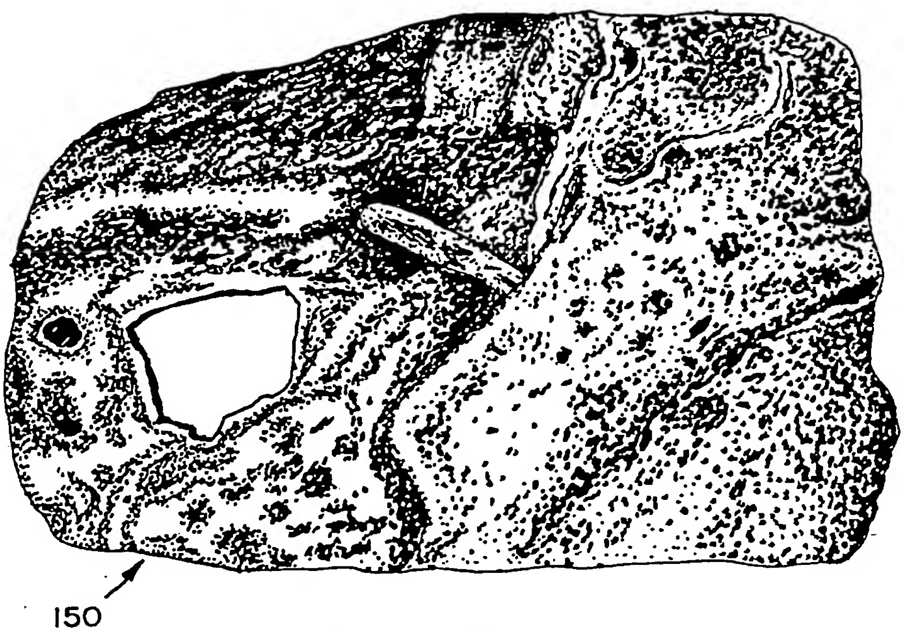

Fig. 12

INTERNATIONAL SEARCH REPORT

PCT/US92/08266

A. CLASSIFICATION OF SUBJECT MATTER

IPC(5) :A61M 5/32,
US CL :604/265
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/265; 606/54,70,76; 623/16G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A, 4,467,590 (Scales et al) 16 October 1984 See entire disclosure.	1-4,6,8-9,11 5,7,10
Y	US,A, 4,054,139 (Crossley) 18 October 1977 See entire disclosure.	1-4,6,8-9,11
A	US,A, 4,923,450 (Maeda et al) 08 May 1990.	
A	US,A, 5,049,140 (Brenner et al.) 17 September 1991.	
A	US,A, 4,743,493 (Sioshansi et al) 10 May 1988.	

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be part of particular relevance

"E" earlier document published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 JANUARY 1993	10 FEB 1993
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer Ngoc-Ho Nguyen MARK BOCKELMAN NGUYEN NGOC-HO INTERNATIONAL DIVISION
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